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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 08/935,717 | 09/23/1997 | MICHAEL CATT | IMIN.P-014 | 8965 |
| 21121 | 7590 | 03/25/2004 | EXAMINER | |
| OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068 | | | PORTNER, VIRGINIA ALLEN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/935,717

Applicant(s)

CATT ET AL.

Examiner

Ginny Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 11-16, 19-22, 25-27 is/are rejected.
- 7) ☐ Claim(s) 17, 18, 23, 24 and 28-36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/935,717.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/7/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 11-36 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2003 has been entered.

Allowable Subject Matter

3. Claims 17-18, 23-24, 28-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Information Disclosure Statement

4. The information disclosure statement filed November 7, 2003 has been considered.
5. The "AAR" reference, Albertson et al, Review Article, does not show a date of publication on the US PTO-1449, the citation is incomplete.

Rejections Withdrawn

6. Claims 12-14 and 16-30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been obviated in light of the amendment of claim 12, to

recite a capability, through the recitation of "wherein an assay result is revealed", rather than requiring the presence of the labeled reagent to be on the porous carrier.

Rejections Maintained

Claim Rejections - 35 USC § 102

7. Claims 11-16, 19-22 and 25-27 rejected under 35 U.S.C. 102(b) as being anticipated by Catt et al (WO95/13531).

Double Patenting

8. Claim 11 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-9 of U.S. Patent No. 6,235,241 and claims 1,5-6 of US Patent 6,451,619. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed claims are species of the instantly claimed genus of kits; the species anticipating the instantly claimed genus; the genus is obvious over an allowed species of invention.

Response to Arguments

9. Applicant's arguments filed November 7, 2003 have been fully considered but they are not persuasive.

10. The obviousness type double patenting rejection, made of record in paper number 22, was not addressed, and therefore maintained for reasons of record.

11. The rejection of claims 11-16, 19-22, 25-27 under 35 USC 102 (b) as being anticipated by WO 95/13531) is traversed on the grounds that page 5, lines 5-10 do not define a means for initiation of the reading device.

12. It is the position of the examiner that the initiation means is positively recited in instant claim 13, to be a contact portion and a switch actuator; this specific embodiment is disclosed in WO95, at page 34, claim 13, lines 29-33; page 24, lines 27-31. This specific means for initiation is encompassed by the independent instant claim 11. The examiner in paper number 22, page 4, paragraphs 3 and 4, cites page and line numbers for this specifically claimed species of invention encompassed by the genus claim 11. WO95 does disclose and anticipate the instantly claimed invention. It was noted that Applicant did not address the portion of WO95' at page 34, claim 13, in the traversal submitted.

13. Applicant asserts that the initiation switch of WO95/ "does not participate in the formation of the lock and key interaction with the assay device".

14. It is the position of the examiner that the claims recite the phrase "means for initiation of the reading device engages the assay device in a lock and key interaction" and is not required in the "formation of the lock and key interaction as argued. Applicant's arguments are not commensurate in scope with the instantly claimed invention. Engaging and forming can define and constitute two different embodiments of an invention, what is claimed is the initiation means must engage not form the lock and key. The term "engages" defines an interactive relationship between the lock and key configuration but does not require the initiation means to form the lock and key configuration, but does require that upon receipt of the assay device the initiation means

must contact a portion of the switch actuator which is a portion of the initiation means (claim limitations set forth in instant claim 13, which depends from independent claim 11), thus only requiring a portion of the initiation means to be in contact with the assay device. The disclosure of WO95 discloses this embodiment as now claimed (see Response to Arguments, incorporated by reference herein, in paper number 22, pages 3-7).

New Claims and Claim Limitations/New Grounds of Rejection

Claim Objections

15. Claims 31-36 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 31-36 directly or indirectly depend from a canceled claim 1 (Claims 31 and 32 both depend from canceled claim 31), and therefore do not further limit an independent claim.

Claim Rejections - 35 USC § 112

16. Claims 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-36 depend from a canceled claim, therefore are unclear as what the missing claim limitations are, are not distinctly claimed.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure; the cited reference are deemed to be duplicative of the applied reference or to teach embodiments that define the state of the art at the time of filing of the instant specification.

1. Catt et al (EP 0653625 (see claims 11-22) and EP0703454 (see claim 7)) are cited to show reading devices with test strips and kits that comprise the devices and test strips.
2. Catt et al (provisional Application 2003/0044317 and 2002/0137220) are cited to show reading devices and a method of use.
3. Catt et al (US Pat. 6,403,380 and 6,454,726) are cited to show test devices and methods.
4. Catt et al (US Pat. 6,234, 974) is cited to show a test kit that comprises an electronic device.
5. Catt et al (US Pat. 5,467,778) is cited to show a method that utilizes a test device.
6. Deuter (US Pat. 5,445,967) is cited to show a device and test strip (see all claims).
7. McGeehan et al (US Pat. 5,411,858) is cited to show a test device with an initiation area (see claims 6-9).
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
March 15, 2004



MARK NAVARRO
PRIMARY EXAMINER